

EXHIBIT 19-a

One aspect of Judge Korman's assignment is beyond this court's capability at present, however. In addition to reviewing the withheld documents for evidence of bad faith, Judge Korman requested that this court "assure that the privilege[d] documents are not merely duplicative of previously-disclosed non-privileged documents." (Minute Entry and Order for July 26, 2006 Status Conference, *available at* docket entry 179). Because the court has not been provided with all previously disclosed documents, no such comparison could be undertaken. To the extent the defendant objects to the disclosure of the privileged documents identified in Appendix B to this opinion on the basis of redundancy, it may submit copies of already produced documents which support its objection for this court's review. Such submissions must be made within five days.

1. Review of Documents for Proper Application of the Deliberative Process Privilege

a. Scope of the Privilege

The common-law deliberative process privilege is a "sub-species" of the work-product privilege, available to the government for purposes of civil discovery. *See Nat'l Council of La Raza v. U.S. Dep't of Justice*, 411 F.3d 350, 356 (2d Cir. 2005) (citation omitted); *Litton Industries, Inc. v. Lehman Bros. Kuhn Loeb Inc.*, 125 F.R.D. 51, 53 (S.D.N.Y. 1989) (citation omitted). When asserted, the privilege shields from disclosure "documents reflecting advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated." *U.S. Dep't of Interior v. Klamath Water Users Protective Ass'n*, 532 U.S. 1, 8 (2001) (citation and internal quotation marks omitted);

accord Nat'l Council of La Raza, 411 F.3d at 356 (citation omitted).⁶ The policy underlying the deliberative process privilege,

[R]ests on the obvious realization that officials will not communicate candidly among themselves if each remark is a potential item of discovery and front page news, and its object is to enhance 'the quality of agency decisions' by open and frank discussion among those who make them within the Government.

Klamath, 532 U.S. at 8-9 (citations omitted). As one court put it, "when [determining] whether an agency properly withheld documents under the deliberative process privilege, the critical question that must be answered is whether 'disclosure of [the] materials would expose an agency's decisionmaking process in such a way as to discourage candid discussion within the agency and thereby undermine the agency's ability to perform its functions.' " *Wilderness Soc'y v. U.S. Dep't of Interior*, 344 F. Supp. 2d 1, 10 (D.D.C. 2004) (quoting *Formaldehyde Inst. v. U.S. Dep't of Health and Human Servs.*, 889 F.2d 1118, 1122 (D.C. Cir. 1989)).

To properly assert the privilege as to inter- or intra-agency documents, the government must satisfy a two-part test, showing that the documents it seeks to shield from disclosure are both "predecisional" and "deliberative." *Nat'l Council of La Raza*, 411 F.3d at 356 (citations omitted). In doing so, however, the government must avoid "conclusory assertion[s]" of the privilege, "where no factual support is provided for an *essential* element of the claimed privilege or shield." *Senate of the Commonwealth of Puerto Rico on Behalf of Judiciary Comm. v. U.S. Dep't of Justice*, 823 F.2d 574, 585 (D.C. Cir. 1987) (citations and internal quotation marks omitted).

⁶See also 5 U.S.C. § 552(b)(5) (otherwise known as "Exemption 5" of the Freedom of Information Act, which incorporates various civil discovery privileges, including the deliberative process privilege, thus allowing the government to withhold "inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency.").

“A document is predecisional when it is prepared in order to assist an agency decisionmaker in arriving at his decision.” *Tigue v. U.S. Dep’t of Justice*, 312 F.3d 70, 80 (2d Cir. 2002) (citation and internal quotation marks omitted). This must be distinguished from a document that is “postdecisional” or one which “set[s] forth the reasons for an agency decision already made.” *Dipace v. Goord*, 218 F.R.D. 399, 403 (S.D.N.Y. 2003) (quoting *Renegotiation Bd. v. Grumman Aircraft Eng’g Dev.*, 421 U.S. 168, 184 (1975)) (additional citation and internal quotation marks omitted). Nor is a document predecisional, if it is “ ‘merely peripheral to actual policy formation.’ ” *Tigue*, 312 F.3d at 80 (citations omitted). Courts have found a document “predecisional” if the agency can “(i) pinpoint the specific agency decision to which the document correlates, (ii) establish that its author prepared the document for the purpose of assisting the agency official charged with making the agency decision, and (iii) verify that the document precedes, in temporal sequence, the decision to which it relates.” *Nat’l Cong. for Puerto Rican Rights ex rel. Perez v. City of New York*, 194 F.R.D. 88, 92 (S.D.N.Y. 2000) (quoting *Providence Journal Co. v. U.S. Dep’t of Army*, 981 F.2d 552, 557 (1st Cir. 1992)) (internal quotation marks omitted); *accord Grand Cent. P’ship, Inc. v. Cuomo*, 166 F.3d 473, 482 (2d Cir. 1999) (citations omitted); *Mitchell v. Fishbein*, 227 F.R.D. 239, 250 (S.D.N.Y. 2005) (citations omitted). Examples of documents considered predecisional for purposes of the privilege are “recommendations, draft documents, proposals, suggestions, and other subjective documents which reflect the personal opinions of the writer rather than the policy of the agency.” *Tigue*, 312 F.3d at 80 (citation and internal quotation marks omitted).

Even these documents, however, may lose their predecisional character “ ‘if . . . adopted, formally or informally, as the agency position on an issue or . . . used by the agency in its

dealings with the public.’ ” *Nat’l Council of La Raza*, 411 F.3d at 356-57 (quoting *Coastal States Gas Corp v. U.S. Dep’t of Energy*, 617 F.2d 854, 866 (D.C. Cir. 1980)). Disclosure is warranted in such circumstances because, as the Supreme Court explained,

The probability that an agency employee will be inhibited from freely advising a decisionmaker for fear that his advice if adopted, will become public is slight. First, when adopted, the reasoning becomes that of the agency and becomes its responsibility to defend. Second, agency employees will generally be encouraged rather than discouraged by public knowledge that their policy suggestions have been adopted by the agency. Moreover, the public interest in knowing the reasons for a policy actually adopted by an agency supports [disclosure].

Id. (quoting *N.L.R.B. v. Sears, Roebuck & Co.*, 421 U.S. 132, 161 (1975)).

A document is “deliberative” if it “actually . . . relate[s] to the process by which policies are formulated.” *Grand Cent. P’ship*, 166 F.3d at 482 (quoting *Hopkins v. HUD*, 929 F.2d 81, 84 (2d Cir. 1991) (quoting *Jordan v. U.S. Dep’t of Justice*, 591 F.2d 753, 774 (D.C. Cir. 1978) (en banc))) (internal quotation marks omitted). To make this determination, courts have found it helpful to look at whether the document “(i) formed an essential link in a specified consultative process, (ii) reflected the personal opinions of the writer rather than the policy of the agency, and (iii) if released, would inaccurately reflect or prematurely disclose the views of the agency.” *Id.* (quoting *Providence Journal Co.*, 981 F.2d at 559 (quoting *Nat’l Wildlife Fed’n v. Forest Serv.*, 861 F.2d 1114, 1118-19 (9th Cir. 1988))) (internal quotation marks omitted). To that end, documents “reflecting advisory opinions, recommendations, and deliberations comprising part of a process by which governmental decisions and policies are formulated,” fall within the class of deliberative documents contemplated by the privilege. *Id.* (quoting *Hopkins*, 929 F.2d at 84-85 (quoting *Sears*, 421 U.S. at 150)) (internal quotation marks omitted).

To be sure, the concern here is whether the documents at issue “reflect the ‘give-and-take of the consultative process.’ ” *Alloco Recycling, Ltd. v. Doherty*, 220 F.R.D. 407, 414 (S.D.N.Y. 2004) (quoting *Judicial Watch, Inc. v. U.S. Postal Serv.*, 297 F. Supp. 2d 252, 263 (D.D.C. 2004)) (additional citations omitted). To qualify for the privilege, however, such “give-and-take must regard opinions on legal or policy matters.” *Id.* at 414 (quoting *Judicial Watch*, 297 F. Supp. 2d at 263) (additional citations and internal quotation marks omitted) (emphasis added). Therefore, even where “give-and-take” involves “comments from an agency employee . . . with respect to the content of documents,” “[i]f the [documents] themselves merely restate facts, and do not involve ‘legal or policy matters,’ any comments or opinions about these same [documents] are not privileged.” *Id.* (quoting *Judicial Watch*, 297 F. Supp. 2d at 263 (quoting *Vaughn v. Rosen*, 523 F.2d 1136, 1143-44 (D.C. Cir. 1975))). By extension then, “purely factual” materials which do not reflect an agency’s deliberations are also not covered by the privilege. *Id.* (citations omitted). Therefore, “[i]f factual portions of a document are ‘severable without compromising the private remainder of the document[],’ then the factual portions must be disclosed, even though the deliberative material remains protected.” *Alloco Recycling, Ltd. v. Doherty*, 220 F.R.D. 407, 412 (S.D.N.Y. 2004) (quoting *EPA v. Mink*, 410 U.S. 73, 91 (1973), *superseded on other grounds by* Pub. L. No. 93-502, 88 Stat. 1561 (1974)).

Lastly, the court emphasizes that the deliberative process privilege, even if properly asserted, does not guarantee nondisclosure. That is to say the privilege is qualified, and must yield to certain competing interests. See *In re Franklin Nat’l Bank Sec. Litig.*, 478 F. Supp. 577, 582 (E.D.N.Y. 1979) (Weinstein, J.). “Foremost is the interest of the litigants, and ultimately of society, in accurate judicial fact finding.” *Id.* (citations omitted). Other competing interests

which the court may take into account are: “(i) the relevance of the evidence sought to be protected; (ii) the availability of other evidence; (iii) the ‘seriousness’ of the litigation and the issues involved; (iv) the role of the government in the litigation; and (v) the possibility of future timidity by government employees who will be forced to recognize that their secrets are violable.” *Id.* at 583 (citations omitted). *Accord In re Subpoena Served Upon Comptroller of Currency, and Secretary of Bd. of Governors of Fed. Reserve Sys.*, 967 F.2d 630, 634 (D.C. Cir. 1992); *Martin v. Valley Nat. Bank of Arizona*, 140 F.R.D. 291, 303-04 (S.D.N.Y. 1991).

Especially applicable to the present matter, and as the *Franklin National Bank* case makes clear, the deliberative process privilege must, at times, yield to the “public interest in opening for scrutiny the government’s decision making process.” *In re Franklin Nat’l Bank Sec. Litig.*, 478 F. Supp. at 582. As Judge Weinstein, quoting the late-Justice Brennan, cogently observed, this limitation is a reflection of a certain “paradox” inherent in the exercise of the deliberative process privilege – that is, “‘to enable the government more effectively to implement the will of the people, the people are kept in ignorance of the workings of their government.’” *Id.* (quoting *Herbert v. Lando*, 441 U.S. 153, 195 (1979) (Brennan, J., dissenting)). “[J]ustification for the privilege [is therefore] attenuated” “when the public’s interest in effective government would be *furthered* by disclosure,” and disclosure is proper. *Id.* (~~emphasis added~~). Of particular relevance, “where the documents sought may shed light on alleged government malfeasance, the privilege is denied.” *Id.* (additional citations omitted).

b. Documents Not Falling Within the Scope of the Privilege

Applying the principles set forth above, the court finds that the documents listed in Appendix A to this opinion are not covered by the privilege. Foremost among these unprivileged

documents are “agendas” or “executive summaries” (draft and final versions) of meetings. These documents typically contain a brief background on the Plan B OTC-switch application process, and a listing of topics for discussion. (*See, e.g.*, Tummino-895-96, 1063-65, 2737-39, 3879-81, 3884-86, 3888-90, 4049-51, 4079-80, 4081-83, 4693-94, 4702-03.)⁷ These documents may of course form the basis for internal deliberations on agency policy. However, as the documents do not disclose what was eventually discussed or indeed whether they were even relied upon by agency officials, these types of documents are neither “predecisional,” *Grand Cent. P’ship*, 166 F.3d at 482 (documents which are “merely peripheral to actual policy formation” are not predecisional) (citation omitted), nor “deliberative,” *id.* (documents which do not reflect personal opinions of the writer are not deliberative) (citations omitted).⁸

As to the other documents listed in Appendix A, the court overrules the assertion of privilege because they are either “purely factual” in nature, in which case their disclosure would raise none of the concerns the privilege was meant to address, i.e., exposure of internal agency deliberations chilling future inter-governmental debate, or have, in one form or other, been “adopted, formally or informally, as the agency position on an issue or . . . used by the agency in its dealings with the public.” *Nat’l Council of La Raza*, 411 F.3d at 356-57 (citation and internal quotation marks omitted).

⁷Citations to the Bates numbers assigned to documents involved in this litigation are in the form of “Tummino-XXXXX.”

⁸The defendant had, at certain junctures of the discovery process, apparently operated under a similar rationale where some of the documents it turned over to the plaintiffs without any claim of privilege also contain agenda-like language. (*See, e.g.*, Tummino-1818-1822, attached to Ex.C of Pls.’ Letter to Mag. J. Pohorelsky, Aug. 29, 2006.)

2. Review of Documents for Evidence of Bad Faith

Having set aside those documents which do not qualify for the privilege, the court turns to a review of the defendant's submission for evidence of bad faith.⁹ That task is of course preceded by defining what "bad faith" means in relation to the present matter. Because of the case's complexity, "bad faith" should not, and indeed, cannot be distilled into a one-line definition. Rather, consistent with the claims pressed by the plaintiffs, and in reliance on past submissions and its February 24, 2006 decision, the court has considered the following five categories of information to be reflective of improper FDA behavior – or in other words, agency bad faith – in considering OTC access to Plan B:

- 1) Involvement in the Plan B OTC-approval process by high-level FDA officials who, historically and statutorily, do not generally participate in OTC-switch proceedings;
- 2) Inappropriate (non-scientific) considerations by FDA officials imported into the Plan B OTC-switch process, including those brought to the FDA's attention by third parties;
- 3) Indications of efforts to chart an unusual course in dealing with the OTC-switch applications, including veiled attempts to delay reaching a final decision;
- 4) Indications that a decision had already been made or that efforts were made to steer the application towards a specific result under the direction of higher level officials before completion of the scientific process;
- 5) Indications of potential retaliation by upper management against FDA employees who disagree with management's views that Plan B OTC-access be restricted.

As stated earlier, the bates numbers of the documents which contain information that falls within one or more of the above categories are listed in Appendix B to this opinion.

⁹Some of the nonprivileged documents listed in Appendix A exhibit evidence of bad faith and are therefore also noted in Appendix B.

To the list in Appendix B the court has also added documents which reflect viewpoints within the FDA opposed to an age-restricted Plan B OTC-distribution plan. While these documents undoubtedly demonstrate a healthy intra-agency debate, thus militating against disclosure, many of the authors have already had their dissenting views aired in public. *See Tummino*, 427 F. Supp. 2d at 220-25, 228-29 (reciting communications from FDA senior review staff which “uniformly and emphatically recommended that the application be approved without restrictions, arguing that the mandate of the FDA did not allow it to consider adolescent sexual behavior in making its decision, and that, in any event, the data submitted by the applicant was sufficient to allay the concerns of the Commissioner.”). As the material at issue has already been disclosed presumably with the consent of the author, or at the very least the agency, there is less risk that agency deliberations would suffer any chilling effect. More importantly, these documents offer clues as to why the FDA reached the result it did despite vocal opposition among many agency employees, and thus shed light on the agency decisionmaking process, the proof of which lies at the heart of the plaintiffs’ case.

3. The Sufficiency of the Defendant’s Privilege Log

Finally, the court turns to a remaining body of documents for which a determination cannot be made concerning the proper application of the privilege. For these documents, listed in Appendix C below (and indeed for the submission as a whole), the court is troubled that the defendant has made no effort to tailor its assertion of the privilege to ensure that only those portions of documents which qualify as *both* deliberative and predecisional are withheld, or to offer any explanation as to why the privilege applies in such a way that entire documents should

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be shielded from disclosure. In essence, the defendant has taken an all-or-nothing approach in asserting the privilege, which has complicated the court's task.

For example, many of the documents in the 1,179-page *in camera* submission seem to contain factual portions which may be segregated from the deliberative portions of the document. In particular, the submission is densely populated with lengthy FDA studies, ranging from 20 to 50 pages, which the defendant contends are entirely privileged. Surely that cannot be the case when large portions of these studies simply recite results from other publicly available scientific studies.¹⁰ Of course, it may turn out that such information, even if disclosed, would be of limited value to the plaintiffs. That, however, does not relieve the defendant of the obligation to avoid blanket assertions of the privilege, which unnecessarily compromise the public's interest in "accurate judicial fact finding." *In re Franklin Nat'l Bank Sec. Litig.*, 478 F. Supp. at 582. Moreover, as the District of Columbia Circuit emphasized in its landmark decision in *Vaughn v. Rosen*, in withholding production of a large document "it is vital that the agency specify in detail which portions of the document are disclosable and which are allegedly exempt." 484 F.2d 820, 827 (D.C. Cir. 1973).

To its credit, the defendant has included, with its extensive *in camera* submission, a privilege log to support its assertions of privilege. *See* Local Civ. R. 26.2(a)(2)(A) (setting forth types of information a litigant must provide when objecting to disclosure of documentary evidence on basis of privilege); *Bowne of New York City, Inc. v. AmBase Corp.*, 150 F.R.D. 465,

¹⁰Many such documents are also described as "drafts" in the privilege log, but bear scant indications that one anticipates seeing in a draft document. In any event, the law is clear that "simply designating a document as a 'draft' does not automatically make it privileged under the deliberative process privilege." *Wilderness Soc'y*, 344 F. Supp. 2d at 14 (citation omitted); *see also* *Judicial Watch, Inc. v. U.S. Postal Serv.*, 297 F. Supp. 2d at 260-61 (finding ambiguities in agency descriptions of draft documents foreclosing summary judgment in FOIA case) (citations omitted).